UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, Plaintiff, v. PREMIER WEIGHT LOSS OF INDIANA, LLC D/B/A PREMIER WEIGHT LOSS, PREMIER WEIGHT LOSS MANAGEMENT, LLC, Defendants.	)	Case No. 1:25-cv-00664-TWP-TAB
PREMIER WEIGHT LOSS MANAGEMENT, LLC, PREMIER WEIGHT LOSS OF INDIANA, LLC D/B/A PREMIER WEIGHT LOSS, Counter Claimants, v. ELI LILLY AND COMPANY, Counter Defendant.	)	

ORDER ON PLAINTIFF'S MOTION TO DISMISS DEFENDANTS' COUNTERCLAIMS

This matter is before the Court on Plaintiff Eli Lilly and Company's ("Lilly") Motion to Dismiss Defendants' Counterclaims (Filing No. 37). Lilly initiated this action alleging trademark infringement and false advertising under the Lanham Act and state law (Filing No. 1). Defendants Premier Weight Loss Management, LLC, and Premier Weight Loss of Indiana, LLC (together, "PWL"), filed Counterclaims alleging defamation and seeking injunctive relief (Filing No. 34). For the reasons stated below, the Motion is **granted in part** and **denied in part**.

I. BACKGROUND

The following facts are not necessarily objectively true, but as required when reviewing a motion to dismiss, the Court accepts as true all factual allegations in the complaint (or in this case, the counterclaims) and draws all inferences in favor of PWL as the non-moving party. *See Bielanski v. Cnty. of Kane*, 550 F.3d 632, 633 (7th Cir. 2008) (standard of dismissal of a complaint); *Cozzi Iron & Metal, Inc. v. U.S. Office Equip., Inc.*, 250 F.3d 570, 574 (7th Cir. 2001) (similar standard for dismissal of a counterclaim). This background section is not intended to be a comprehensive presentation of the facts of the case. Rather, the Court recites only those facts pertinent to the Counterclaims.

Lilly manufactures and sells Mounjaro® and Zepbound®, which are injectable solutions approved by the Federal Drug Administration ("FDA") (Filing No. 34 at 3). Mounjaro® is FDA-approved for the treatment of type 2 diabetes mellitus, and Zepbound® is FDA-approved for the treatment of obesity and obstructive sleep apnea. *Id.* Both medicines were approved for distribution in, and are distributed in, Lilly's factory-sealed single-dose autoinjector pens containing 0.5mL of tirzepatide fluid in various strengths. *Id.* at 3–4.

PWL is a medical practice located in Indianapolis that employs a team of medical professionals to help patients achieve their weight loss goals. *Id.* at 5. At the conclusion of an in-person appointment with a patient, PWL can provide the patient with Mounjaro® or Zepbound® onsite by purchasing the drugs through licensed wholesalers and then providing the patient directly with the medicine. *Id.* at 6. PWL can also send a prescription to a third-party pharmacy for the patient to pick up. *Id.*

PWL's medical team prescribes lower and/or different doses than what patients are able to obtain through the autoinjectors. *Id.* at 7. To do this, PWL repackages the Mounjaro® and

Zepbound® medicines from the autoinjectors into third-party insulin syringes containing the new dosage (Filing No. 33 at 25 ¶56). The third-party insulin syringes contain different labeling and package inserts, which have not been approved by the FDA. *Id.* at 23 ¶52. PWL sells the syringes to patients and represents that they are genuine Mounjaro® and Zepbound®. *Id.* at 38–40.

On April 7, 2025, Lilly filed a Complaint against PWL alleging trademark infringement and false and misleading advertising under the Lanham Act and state law (Filing No. 34 at 9). Around that time, Lilly published its Complaint to third parties. *Id.* at 10. For example, PWL received a voicemail on April 6, 2025, from a reporter at The Pink Sheet, which provides in-depth coverage of the prescription pharmaceutical industry, requesting a comment on a lawsuit by Lilly against PWL regarding Zepbound® and Mounjaro®. *Id.* And at 5:00 a.m. on April 7, 2025, four hours after Lilly filed its Complaint in this case, Indianapolis-based news station WTHR published an article specifically naming PWL and reporting that "[Lilly] says it's suing an Indianapolis-based weight loss clinic that it claims is misleading patients about drugs being sold." *Id.* WTHR also reported that Lilly issued the following statement: "We will continue to take action to stop these illegal actors and urgently call on regulators and law enforcement to do the same." *Id.* However, WTHR retracted that report and revised its story to clarify that this statement was made about different lawsuits involving different parties rather than this one, expressing "regret" about "any possible confusion between the two cases." (Filing No. 38 at 12).

On June 6, 2025, PWL filed Counterclaims against Lilly, alleging Count I: Defamation and Defamation *Per Se*, and Count II: Injunctive Relief (Filing No. 34).

II. LEGAL STANDARD

The legal standard for a motion to dismiss a counterclaim is the same as for a motion to dismiss a complaint. *Cozzi Iron & Metal Inc. v. U.S. Office Equip., Inc.*, 250 F.3d 570, 574 (7th

Cir. 2001). Federal Rule of Civil Procedure 12(b)(6) allows a defendant to move to dismiss a complaint that has failed to "state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). When deciding a motion to dismiss under Rule 12(b)(6), the Court accepts as true all factual allegations in the complaint and draws all inferences in favor of the plaintiff. *Bielanski*, 550 F.3d at 633. However, courts "are not obliged to accept as true legal conclusions or unsupported conclusions of fact." *Hickey v. O'Bannon*, 287 F.3d 656, 658 (7th Cir. 2002).

The complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). In *Bell Atlantic Corp. v. Twombly*, the United States Supreme Court explained that the complaint must allege facts that are "enough to raise a right to relief above the speculative level." 550 U.S. 544, 555 (2007). Although "detailed factual allegations" are not required, mere "labels," "conclusions," or "formulaic recitation[s] of the elements of a cause of action" are insufficient. *Id.*; *see also Bissessur v. Ind. Univ. Bd. of Trs.*, 581 F.3d 599, 603 (7th Cir. 2009) ("it is not enough to give a threadbare recitation of the elements of a claim without factual support"). The allegations must "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Twombly*, 550 U.S. at 555. Stated differently, the complaint must include "enough facts to state a claim to relief that is plausible on its face." *Hecker v. Deere & Co.*, 556 F.3d 575, 580 (7th Cir. 2009) (citation and quotation marks omitted). To be facially plausible, the complaint must allow "the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citing *Twombly*, 550 U.S. at 556).

When considering a motion to dismiss, "a court may consider, in addition to the allegations set forth in the complaint itself, documents that are attached to the complaint, documents that are

central to the complaint and are referred to in it, and information that is properly subject to judicial notice." *Williamson v. Curran*, 714 F.3d 432, 436 (7th Cir. 2013).

III. DISCUSSION

Before discussing the merits of Count I: Defamation and Defamation *Per Se*, the Court must dismiss Count II: Injunctive Relief of the Counterclaims. "With respect to injunctive relief, that is a remedy, not a cause of action, and thus should not be pleaded as a separate count." *Knutson v. Vill. of Lakemoor*, 932 F.3d 572, 576 n.4 (7th Cir. 2019). If PWL prevails on Count I, then it may be entitled to injunctive relief, but injunctive relief is not a stand-alone claim. Accordingly, the Motion to Dismiss Defendants' Counterclaims is **granted in part**, and Count II is **dismissed**.

PWL alleges in Count I that Lilly defamed it by asserting three different statements (collectively, the "Asserted Statements"):

> 1. Lilly stated that PWL is an "illegal actor" such that "regulators and law enforcement" should take action against it ("Asserted Statement #1");
>
> 2. Lilly's Complaint states that PWL is putting its patients' lives at risk ("Asserted Statement #2"); and
>
> 3. Lilly's Complaint states that PWL breaks apart or cracks open Lilly's autoinjector pens ("Asserted Statement #3").

(Filing No. 34 at 19). PWL alleges these statements are false, and that Lilly's statement that PWL is an "'illegal actor' . . . constitutes defamation per se because it imputes (1) criminal conduct to PWL and (2) misconduct in PWL's trade, profession, office, and occupation." *Id.* PWL also alleges that this statement constitutes defamation *per quod* because it has a defamatory imputation, was made with malice, was published, and caused damages to PWL.

Under Indiana law, a defamatory communication is one that "tends to harm a person's reputation by lowering the person in the community's estimation or deterring third persons from dealing or associating with the person." *Kelley v. Tanoos*, 865 N.E.2d 593, 596 (Ind. 2007) (citation

and internal quotations omitted). A defamatory statement can be either defamatory *per se* or defamatory *per quod*. *Id.* "A communication is defamatory *per se* if it imputes: (1) criminal conduct; (2) a loathsome disease; (3) misconduct in a person's trade, profession, office, or occupation; or (4) sexual misconduct." *Id.* (citation omitted).

To maintain an action for defamation *per se* or defamation *per quod*, a plaintiff must satisfy four elements: (1) a communication with defamatory imputation; (2) malice; (3) publication; and (4) damages. *Id.* at 596–97 (citation omitted). The key difference between defamation *per se* claims and defamation *per quod* claims relates to damages; that is, a *per se* plaintiff "is entitled to presumed damages as a natural and probable consequence of the *per se* defamation." *Id.* at 597 (citation and internal quotations omitted). Whether a communication is defamatory is a question of law for the Court, unless the communication is susceptible to both a defamatory and a non-defamatory interpretation. *Id.* at 596.

Lilly contends that in PWL's Answer and Counterclaim, PWL unequivocally admits to conduct that is, in fact, illegal not just under federal and state unfair competition laws, but also under the Food, Drug & Cosmetic Act (FDCA) and corresponding Indiana statutes (Filing No. 38 at 7). Lilly argues that PWL's counterclaims fail as a matter of law for two reasons: (1) PWL's own allegations and answers admit to the unlawful conduct that the Asserted Statements describe; and (2) the Asserted Statements are protected by Indiana's litigation privilege. *Id.* at 14.

PWL argues that Lilly's affirmative defenses are premature, and even if the Court finds that such defenses are not premature, they fail nonetheless (*see* Filing No. 39). The Court will address whether Lilly's defenses are premature and then the merits of each defense.

A. Whether Lilly's Defenses Are Premature

PWL contends that Lilly's affirmative defenses "are not a proper basis for dismissal under Fed. R. Civ. P. 12(b)(6) because Lilly has not yet pleaded—and has the burden of proving—those affirmative defenses." (Filing No. 39 at 6 (citing *Rackemann v. LISNR, Inc.*, No. 17-cv-624, 2018 U.S. Dist. LEXIS 163618, at *23 (S.D. Ind. Sept. 2018))). Lilly responds that "[c]ourts must dismiss defamation claims where 'the plaintiff more or less concedes the essential truth of the allegedly defamatory statement' or the allegedly defamatory statement was 'substantially true even as framed in the plaintiff's own allegations.'" (Filing No. 38 at 14 (quoting *Myers v. Phillips Chevrolet, Inc.*, No. 04 C 0763, 2004 U.S. Dist. LEXIS 21635, at *17 (N.D. Ill. Oct. 25, 2004))).

"The mere presence of a potential affirmative defense does not render the claim for relief invalid. Further, these defenses typically turn on facts not before the court at that stage in the proceedings." *Brownmark Films, LLC v. Comedy Partners*, 682 F.3d 687, 690 (7th Cir. 2012). Accordingly, "it is typically premature for a court to dismiss a complaint on an affirmative defense unless 'the allegations of the complaint itself set forth everything necessary to satisfy the affirmative defense.'" *Brown v. Indianapolis Metro. Police Dep't*, No. 18-cv-3157, 2019 U.S. Dist. LEXIS 133377, at *2 (S.D. Ind. Aug. 2019) (quoting *United States v. Lewis*, 411 F.3d 838, 842 (7th Cir. 2005)).

Here, as the Court will discuss below, all relevant facts necessary to plausibly establish Lilly's affirmative defenses for Asserted Statement #1 and Asserted Statement #3 are contained in PWL's Answer and Counterclaims. The Court also agrees with Lilly that a motion to dismiss a defamation claim on grounds of truth is proper "if the plaintiff more or less concedes the essential truth of the allegedly defamatory statement, or if there is no basis for a reasonable jury to find that the allegedly defamatory statement was not substantially true even as framed in the plaintiff's own

allegations." *Myers*, 2004 U.S. Dist. LEXIS 21635, at *17 (citing *Clark v. Maurer*, 824 F.2d 565, 566 (7th Cir. 1987)).

However, Defendants' Answer and Counterclaims do not concede facts that establish Lilly's affirmative defenses concerning Asserted Statement #2—that PWL is putting its patients' lives at risk—so the Motion to Dismiss Defendants' Counterclaims is **denied** as to Asserted Statement #2.

The Court now turns to the merits of Lilly's truthfulness and litigation privilege defenses.

B. Lilly's Defense of Truthfulness

To be held liable for defamation, a defendant must make a false statement of fact. *See Journal-Gazette Co., Inc. v. Bandido's, Inc.*, 712 N.E.2d 446, 457 (Ind. 1999) (citing *Heeb v. Smith*, 613 N.E.2d 416, 420 (Ind. Ct. App. 1993)). While truth is a defense to defamation, the literal truth is not required. *See Masson v. New Yorker Magazine, Inc.*, 501 U.S. 496 (1991); *Heeb*, 613 N.E.2d at 420. A statement is sufficiently true if it has a "substantial basis in the truth" and if the "gist" or "sting" of the statement is true. *Brandom v. Coupled Prods.*, 975 N.E.2d 382, 390–91 (Ind. Ct. App. 2012); *Heeb*, 613 N.E.2d at 421. "The test for determining whether a statement is substantially true is whether any inaccuracies caused the statement to produce a different effect on the audience than would have been produced had the literal truth been spoken." *Heeb*, 613 N.E.2d at 421; *see also Bandido's*, 712 N.E.2d at 457.

Lilly argues that PWL fails to allege a false statement of fact because PWL admits to the unlawful conduct contained in the Asserted Statements in both its Answer and Counterclaims (Filing No. 38 at 15). Specifically, Lilly argues that PWL admits to "tamper[ing]" with Lilly's medicines by removing the contents of Lilly's autoinjector pens, putting the contents in syringes, and selling the syringes as Lilly products using Lilly's trade names. *Id.*; (Filing No. 33 at 25 ¶56).

PWL responds that Lilly falsely asserts that it breaks or cracks open autoinjector pens, destroys sterility, and fails to provide its patients with FDA-approved information in its inserts (Filing No. 39 at 14). PWL argues that Lilly likens its conduct to that of compounding pharmacies whose gross negligence has caused patient deaths and resulted in criminal prosecutions, and that Lilly accuses PWL of engaging in an illicit scheme, deceiving its patients, putting patients' lives at risk, and doing so for profit. According to PWL, these statements accuse it of criminal conduct and professional misconduct, and because Lilly cannot prove that PWL violated a criminal statute, Lilly's truthfulness defense fails. The Court disagrees.

First, PWL alleges that it "dispenses" Lilly's products into third-party syringes and sells them as Mounjaro® and Zepbound® (Filing No. 34 at 7 ¶31; Filing No. 33 at 25 ¶56). This admission supports Lilly's assertion that PWL breaks apart or cracks open Lilly's autoinjector pens. While PWL takes issue with the use of the verbiage "breaks apart" or "cracks open," such language is synonymous with PWL's admission of "repackag[ing]" Lilly's autoinjector pens into third-party insulin syringes. Accordingly, the "gist" or "sting" of Lilly's statement is true, and thus, Lilly's truthfulness defense is successful for Asserted Statement #3.

Second, PWL contends that Asserted Statement #1—that PWL is an "illegal actor" such that "regulators and law enforcement" should take action—imputes criminal conduct. PWL argues the assertion that "regulators *and law enforcement*" should take action leads to an ambiguity which must be resolved in PWL's favor as the non-moving party and therefore construed to mean that Lilly alleged that PWL acted criminally (Filing No. 39 at 13 (emphasis in original)). This argument is misplaced.

While the Court agrees that "illegal conduct" includes criminal conduct, "[t]he Seventh Circuit has explicitly rejected the suggestion that only a criminal act may be 'illegal conduct.'"

Smith v. Biomet, Inc., 384 F. Supp. 2d 1241, 1252 (N.D. Ind. 2005) (citing *Syndicate Sales, Inc. v. Hampshire Paper Corp.*, 192 F.3d 633, 641 (7th Cir. 1999)). The Seventh Circuit in *Syndicate Sales* explained that "courts interpreting Indiana law have held that non-criminal illegal acts are sufficient" to establish the illegality requirement for tort claims. 192 F.3d at 641 (holding that dilution of a trademark could be "illegal conduct" sufficient to establish illegality). Accordingly, if PWL's conduct is unlawful, whether criminal or otherwise, Lilly's defense of truthfulness will be successful for Asserted Statement #1.

Lilly also argues that PWL's admitted conduct violates the Lanham Act, the Food, Drug, and Cosmetic Act ("FDCA"), and analogous Indiana state laws (Filing No. 38 at 16). The Court will address each alleged federal violation, with its state law analog, in turn.

1. The Lanham Act

"Congress passed the Lanham Act in 1946 to 'federalize' existing common law protection of trademarks used in interstate commerce." *CAE, Inc. v. Clean Air Eng'g, Inc.*, 267 F.3d 660, 672 (7th Cir. 2001). Under the Lanham Act, a defendant is liable for federal trademark infringement and counterfeiting if the defendant:

> [W]ithout the consent of the registrant . . . use[s] in commerce any reproduction, counterfeit, copy, or colorable imitation of a registered trademark in connection with the sale, offering for sale, distribution, or advertising of any goods or services or in connection with which such use is likely to cause confusion, or to cause mistake, or to deceive.

Desmond v. Chi. Boxed Beef Distribs., 921 F. Supp. 2d 872, 889–80 (N.D. Ill. 2013) (quoting 15 U.S.C. § 1114(1)(a). The Lanham Act further imposes liability upon:

> Any person who, on or in connection with any goods or services . . . uses in commerce any . . . false designation of origin, false or misleading description of fact, or false or misleading misrepresentation of fact, which is likely to cause confusion or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods . . . by another person.

Id. (quoting 15 U.S.C. § 1125(a)(1)(A)).

All relevant authority uses the same analysis for Indiana unfair competition claims based on trademarks and Lanham Act trademark claims. *Fortres Grand Corp. v. Warner Bros. Entertainment Inc.*, 763 F.3d 696, 700 n.4 (7th Cir. 2014) (citing cases). "The state's law therefore tracks the terminology of the Lanham Act almost identically, and the essential elements of a state claim are the same as those of a federal one," with one difference not relevant here. *Heckler & Koch, Inc. v. German Sport Guns GmbH*, 71 F. Supp. 3d 866, 924 (S.D. Ind. 2014) (citing *Serenity Springs v. LaPorte Cnty. Convention & Visitors Bureau*, 986 N.E.2d 314, 323 (Ind. Ct. App. 2013)). Accordingly, the Court analyzes Lilly's defense of truthfulness for violation of the Lanham Act and analogous state law together.

To prevail on a claim for trademark infringement and counterfeiting under 15 U.S.C. § 1114(1)(a), or for unfair competition under 15 U.S.C. § 1125(a)(1)(A), a plaintiff must prove two elements. *See* 15 U.S.C. § 1125(a); *Segal v. Geisha NYC LLC*, 517 F.3d 501, 506 (7th Cir. 2008). First, the plaintiff must establish that "its mark is protected under the Lanham Act"; second, that the challenged mark is likely to cause confusion among consumers. *Barbecue Marx, Inc. v. 551 Ogden, Inc.*, 235 F.3d 1041, 1043 (7th Cir. 2000). The parties do not dispute that Lilly's Mounjaro® and Zepbound® marks are protected under the Lanham Act. Rather, the parties argue about the second element.

Lilly argues that PWL materially alters Lilly's products before selling such products under Lilly's marks by "remov[ing] the good from its original packaging," putting the contents in a different delivery mechanism, and selling it "in packaging that is not approved by the trademark owner's quality controls." (Filing No. 38 at 17 (quoting *Nutradose Labs, LLC v. Bio Dose Pharma*, No. 22-cv-20780, 2023 U.S. Dist. LEXIS 92011, at *47 (S.D. Fla. May 25, 2023))). Lilly asserts

that PWL admits to changing the risk information and labels that accompany Lilly's medicines, as well as certain disclosures and instructions for use, thus materially altering the product. *Id.* PWL responds that its admissions do not establish confusion because PWL's Answer "merely stated that it *sometimes* provides [Mounjaro®/Zepbound®] purchased from Lilly through an authorized wholesaler directly to patients who select that option," which do not admit actual confusion (Filing No. 39 at 23). Rather, such admissions merely show that PWL's patients have two options—autoinjectors or syringes—from which to choose after both options are explained by a PWL medical provider. *Id.*

The Court is persuaded that the pleadings contain sufficient facts to support Lilly's claim that PWL's conduct violates the Lanham Act. "[T]hose who resell genuine trademarked products are generally not liable for trademark infringement." *McCarthy v. Fuller*, No. 1:08-cv-994, 2013 U.S. Dist. LEXIS 162826, at *5 (S.D. Ind. Nov. 15, 2013) (citing cases). "'The reason is that trademark law is designed to prevent sellers from confusing or deceiving consumers about the origin or make of a product, which confusion ordinarily does not exist when a genuine article bearing a true mark is sold.'" *Id.* (quoting *NEC Elecs. V. CAL Circuit Abco*, 810 F.2d 1506, 1509 (9th Cir. 1987)).

However, "[p]roducts sold outside a manufacturer's authorized distribution system are not genuine products unless sold in their original packaging, within expiration dates, and otherwise sold consistent with the manufacturer's quality controls pursuant to the 'first sale' date." *Std. Process, Inc. v. AVC Infinite, LLC*, No. 18 cv-849, 2020 U.S. Dist. LEXIS 5098, at *12–13 (W.D. Wisc. Jan. 9, 2020) (citing cases). "This follows because '[o]ne of the most valuable and important protections afforded by the Lanham Act is the right to control the quality of the goods manufactured and sold under the holder's trademark.'" *Id.* (quoting *Warner-Lambert Co. v.*

Northside Dev. Corp., 86 F.3d 3, 6 (2d Cir. 1996)). Accordingly, "the actual quality of the goods is irrelevant; it is the control of quality that a trademark holder is entitled to maintain." *Safety Socket LLC v. Relli Tech., Inc.*, No. 18-cv-6670, 2023 U.S. Dist. LEXIS 84143, at *16 (N.D. Ill. May 15, 2023) (cleaned up).

Here, PWL does not sell genuine products because it admits that it "repackage[s] [Lilly's] medicines into third-party insulin syringes." (Filing No. 33 at 25 ¶56). Such conduct is also likely to cause confusion because PWL advertises that it only sells "name brand, FDA approved weight loss injections," just the "authentic," "real stuff," and "FDA approved brand name GLP-1 injections like Mounjaro [and] Zepbound." *Id.* at ¶2. While PWL contends that its patients are still receiving Mounjaro® and Zepbound®, which are repacked "in a controlled aseptic environment pursuant to widely accepted standard operating procedures," (Filing No. 39 at 23), these contentions misunderstand the purpose of the Lanham Act. The purpose of the Lanham Act is to afford the trademark holder the right to control the quality of the goods manufactured and sold under its trademark. *Std. Process*, 2020 U.S. Dist. LEXIS 5098, at *12–13. It is not enough for PWL to claim that its unauthorized use comports with widely accepted standards. Rather, it is Lilly, as the trademark holder, who is afforded the exclusive right to determine the quality control standards.

This makes sense, as the Court can think of no circumstance where quality control is more imperative to a trademark holder than in the production of medicine. Any negative outcome or complication a patient experiences when taking Mounjaro® or Zepbound® is likely to be directly attributed to the medicine and, thus, Lilly. Accordingly, Lilly has an immense interest in the quality control of every dose of Mounjaro® or Zepbound®. Dispensing the contents of Lilly's medicines into third-party syringes and changing the packaging, labeling, and dosages contained therein, plausibly violates both the language and the purpose of the Lanham Act.

2. The FDCA

Lilly argues that even if it had called PWL's conduct criminal, as PWL suggests, such statement would also be substantially true because PWL created a "new drug," as that term is defined in the FDCA, by repackaging Lilly's medicines into third-party insulin syringes for which PWL never received FDA approval, but passed its unapproved, repackaged drugs off as the FDA-approved, genuine Lilly medicines, violating at least 21 U.S.C. §§ 352(a)(1), 352(i)(l)–(3), 352(n), and Indiana's analogous misbranding statute, Ind. Code § 16-42-3-4, all of which are criminal statutes (Filing No. 38 at 20–21). PWL argues in its Response that "[a]t most, PWL admits that its doctors and nurse practitioners use their clinical judgment in prescribing non-FDA-approved doses of Mounjaro/Zepbound for *some* patients." (Filing No. 39 at 22 (emphasis in original)). PWL surmises that such conduct "*may* amount to the off-label prescription of these drugs, [but] it is common practice and does not violate any law. To the extent certain doses are not FDA-approved, that is because Lilly chose not to seek approval for those dosages; it does not inherently mean those dosages are unsafe or put patients at risk." *Id.* (emphasis in original). The Court concludes that PWL's conduct violates the FDCA.

Whether PWL violated the FDCA does not turn on a finding that certain dosages are "unsafe or put patients at risk," nor does it turn on whether PWL provided "off-label" prescriptions. Rather, 21 U.S.C. § 355(a) states, "[n]o person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application . . . is effective with respect to such drug." *Id.* The term "new drug" means "[a]ny drug . . . the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed," or "[a]ny drug . . . the composition of which is such that such drug, as a

result of investigations to determine its safety and effectiveness for use under such conditions has become so recognized, but which has not . . . been used to a material extent or for a material time under such conditions." 21 U.S.C. §§ 321(p)(1)–(2).[1]

> A new drug may arise by reason of:
>
> (3) The newness for drug use of the proportion of a substance in a combination, even though such combination containing such substance in other proportion is not a new drug[, or] . . .
>
> (5) The newness of a dosage, or method or duration of administration or application, or other condition of use . . . even though such drug when used in other dosage, or other method or duration of administration or application, or different condition, is not a new drug.

21 C.F.R. 310.3(h)(3), (5). "In *United States v. Generix Drug Corp.*, 460 U.S. 453 (1983), the Supreme Court held that the term 'drug' as used in the FDCA refers not only to the active ingredient in a drug product, but to the entire product." *United States v. Baxter Healthcare Corp.*, 901 F.2d 1401, 1409 (7th Cir. 1990) (citation omitted). The Supreme Court rejected an argument by a generic drug distributor that a "drug" means only the "active ingredient," not including the "excipients" such as coatings and capsules. *Id.* Instead, "[t]he Supreme Court read the language of 21 U.S.C. § 321(g)(1), which defines the term 'drug,' as 'quite plainly' encompassing generic drug products in their entirety." *Id.* (citing *Generix*, 460 U.S. at 458–459). While the Supreme Court in *Generix* did not reach the issue of whether two bioequivalent products, containing the same active ingredients but different excipients, are the same "drug," the Seventh Circuit has stated that "[a]pproval by the FDA constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards and labeling. The FDA's determination is specific to the product." *Mitchell v. Collagen Corp.*, 126 F.3d 902, 913 (7th Cir. 1997).

[1] There are exceptions to the new drug approval requirement for "compounded" drugs made in compliant pharmacies or outsourcing facilities. *See generally* §§ 353a, 353b. However, PWL's Counterclaim states that it does not compound drugs (Filing No. 34 at 8 ¶40), and PWL does not argue in its Response that its conduct falls within these exceptions.

Neither party disputes that the FDCA contains criminal penalties. *See* 21 U.S.C. § 333. PWL alleges and admits that it repackages Lilly's medicines into third-party insulin syringes, removes Lilly's labeling and package inserts, and provides its own labeling and package inserts that have not been approved by the FDA (Filing No. 34 at 7 ¶31; Filing No. 33 at 23 ¶52). As the Supreme Court held in *Generix*, FDA approval is not merely approval of the active ingredient such that any administration of the active ingredient constitutes the same drug under the FDCA. 460 U.S. at 458–459. PWL's conduct alters the manufacturing methods and labeling of the product. Accordingly, PWL created a "new drug," as that term is defined under the FDCA, failed to obtain FDA approval for its new drug, and sold it to consumers under the guise that the drug was authentic FDA approved Mounjaro® or Zepbound®. Such conduct violates the FDCA—specifically 21 U.S.C. § 355(a), at least.

Based on PWL's Answer and Counterclaims, the Court concludes that Lilly's defense of truthfulness succeeds for Asserted Statement #1—that PWL is an "illegal actor"—and Asserted Statement #3—that PWL "cracks open" Lilly's autoinjector pens. For the reasons discussed above, Lilly sufficiently alleges that PWL violated both the Lanham Act and the FDCA. Even if Lilly stated that PWL was a criminal actor, such statement was substantially true. Further, dispensing Lilly's medicines from their autoinjector packaging is sufficiently synonymous with "crack[ing] open" the medicines. Lilly's Motion to Dismiss Defendants' Counterclaims is therefore **granted in part** as to Asserted Statement #1 and Asserted Statement #3.

However, while Lilly argues that PWL did not deny that FDA guidance indicates that repackaging sterile injectables can put lives at risk, thus making Asserted Statement #2 substantially true (Filing No. 38 at 15), there are not enough facts in the record to conclude that PWL more or less "concede[d] the essential truth" of this statement. *Myers*, 2004 U.S. Dist. LEXIS

21635, at *17. While the literal truth is not required for a truthfulness defense, *see Heeb,* 613 N.E.2d at 420, the statements contained in PWL's Answer and Counterclaims do not lead to the conclusion that PWL conceded patients' lives were at risk. As the Court discussed above, dismissal of the counterclaim concerning this statement would be premature. A material question of fact remains as to whether Lilly's defense of truthfulness may succeed for Asserted Statement #2—that PWL's conduct puts its patients' lives at risk—so the Motion to Dismiss is **denied in part** as to that statement.

C. Lilly's Defense of Indiana's Litigation Privilege

Lilly argues that the Asserted Statements contained in the Complaint are protected by Indiana's absolute litigation privilege (Filing No. 38 at 21). PWL concedes that the Asserted Statements contained in the Complaint would have been subject to the absolute privilege if the Complaint was merely filed (Filing No. 50 at 29:1–8). However, PWL argues that because its Counterclaim alleges that Lilly published the Complaint to various news stations prior to ever filing the lawsuit, the absolute privilege is abrogated (Filing No. 39 at 26). Lilly then contends that even if it disseminated the Complaint to news stations prior to the filing of the lawsuit, Indiana's absolute privilege applies (Filing No. 38 at 23). The Court concludes that based on PWL's allegations in the Counterclaim, the absolute privilege does not apply.

"'Indiana law has long recognized an absolute privilege that protects all relevant statements made in the course of a judicial proceeding, regardless of the truth or motive behind the statements.'" *Rain v. Rolls-Royce Corp.*, 626 F.3d 372, 376 (7th Cir. 2010) (quoting *Hartman v. Keri*, 883 N.E.2d 774, 777 (Ind. 2008)). "'The purpose for the privilege is to preserv[e] the due administration of justice by providing actors in judicial proceedings with the freedom to participate without fear of future defamation claims.'" *Id.* (alteration in original) (quoting *Hartman*, 883

N.E.2d at 777). "[T]he privilege recognizes that the 'public['s] interest in the freedom of expression by participants in judicial proceedings, uninhibited by the risk of resultant suits for defamation, is so vital and necessary to the integrity of our judicial system that it must be made paramount to the right of the individual to a legal remedy when he has been wronged." *Id.* at 376–77(alteration in original) (quoting *Miller v. Reinert*, 839 N.E.2d 731, 735 (Ind. Ct. App. 2005)).

Here, PWL alleges that "Lilly improperly published to third parties the [C]omplaint prior to or contemporaneously with its filing." (Filing No. 34 at 10 ¶55). PWL then alleges that it was contacted by a reporter concerning the lawsuit before the suit had ever been filed. *Id.* at 10 ¶56. Based on the allegations in the Counterclaim, which the Court takes as true, the Court concludes that the absolute privilege does not extend to the Complaint. Lilly argues that this Court has stated that Indiana law mirrors the Restatement of Torts, which "allows parties in private litigation to publish defamatory matter concerning another in communications preliminary to a proposed judicial proceeding, or in the institution of or during the course and as a part of, a judicial proceeding in which he participates, if the matter has some relation to the proceeding." *Id.* (citing *PNC Bank, N.A. v. OCMC, Inc.*, No. 06-cv-755, 2010 U.S. Dist. LEXIS 98368, at *23–24 (S.D. Ind. Sept. 20, 2010)). But such privilege does not extend to the dissemination of the Complaint to the various news stations prior to filing this lawsuit.

"Although Indiana Courts recognize the litigation privilege in regards to communications made in the course of judicial proceedings, they have not extended the privilege to communications made preliminary to a proposed judicial proceeding." *Med. Informatics Eng'g, Inc. v. Orthopaedics Northeast, P.C.*, 458 F. Supp. 2d 716, 728 (N.D. Ind. 2006). Indeed, the Seventh Circuit noted that "the Indiana courts have never extended this privilege, as § 587 of the Restatements does, to statements made *prior* to a judicial proceeding." *Raybestos Prods. Co. v. Younger*, 54 F.3d 1234,

1245 (7th Cir. 1995) (emphasis in original). Accordingly, this privilege does not extend to defamatory statements contained in a complaint if that complaint is published, circulated, or disseminated to persons entirely unrelated to the litigation. *See Associates Fin. Servs. Co., Inc. v. Bowman, Heintz, Boscia & Vician, P.C.*, No. IP99-1725-C-M/S, 2001 U.S. Dist. LEXIS 7874, at *27 (S.D. Ind. April 25, 2001) (concluding that "the act of mailing the complaint to persons unrelated to the litigation is not protected by the absolute privilege."); *see also Asay v. Hallmark Cards, Inc.*, 594 F.2d 692, 698 (8th Cir. 1979) ("[W]hile a defamatory pleading is privileged, that pleading cannot be a predicate for dissemination of the defamatory matter to the public or third parties not connected with the judicial proceeding. Otherwise, to cause great harm and mischief a person need only file false and defamatory statements as judicial pleadings and then proceed to republish the defamation at will under the cloak of immunity.").

Because PWL alleges that Lilly disseminated the Complaint prior to the filing of the lawsuit, PWL has sufficiently pled that Indiana's absolute privilege does not apply. Whether Lilly actually disseminated the Complaint prior to or during the lawsuit is a question that can be tested on summary judgment.

Having concluded that Indiana's litigation privilege does not apply to the Asserted Statements, the Court turns to whether any of the Asserted Statements has survived dismissal. PWL has not sufficiently pleaded allegations to support a claim of defamation and defamation *per se* against Lilly, as Lilly's truthfulness defense is successful for Asserted Statement #1 and Asserted Statement #3, and dismissal is **granted** as to these statements. However, when viewed in a light most favorable to PWL, its counterclaim of defamation for Asserted Statement #2—that PWL is putting its patients' lives at risk—is plausible on its face because neither of Lilly's defenses succeed

at this stage of the proceedings. Dismissal is **denied** as to PWL's defamation counterclaim concerning this statement.

IV. CONCLUSION

For the reasons explained in this Order, Lilly's Motion to Dismiss Defendants' Counterclaims (Filing No. 37) is **GRANTED IN PART and DENIED IN PART**. The Motion is **granted** as to Count II: Injunctive Relief in its entirety and as to Count I: Defamation & Defamation *Per Se* for PWL's claims concerning Asserted Statement #1—Lilly calling PWL an "illegal actor"—and Asserted Statement #2—Lilly alleging that PWL breaks apart or cracks open Lilly's medicines. These counterclaims are **dismissed**.

The Motion is **denied** as to Count I: Defamation & Defamation *Per Se* for PWL's claim concerning Asserted Statement #2—Lilly's statement that PWL is putting its patients' lives at risk. This counterclaim shall proceed.

SO ORDERED.

Date: 12/31/2025

Hon. Tanya Walton Pratt, Judge
United States District Court
Southern District of Indiana

Distribution:

Adam Arceneaux
Ice Miller LLP
adam.arceneaux@icemiller.com

James R.P. Hileman
Kirkland & Ellis LLP
james.hileman@kirkland.com

Irwin B. Levin
COHEN & MALAD LLP
ilevin@cohenandmalad.com

Michael Wesley McBride
COHEN & MALAD LLP
mmcbride@cohenandmalad.com

Robin McCue
Kirkland & Ellis LLP
robin.mccue@kirkland.com

Ryan J. Moorman
Kirkland & Ellis LLP
ryan.moorman@kirkland.com

Edward B. Mulligan, V
COHEN & MALAD LLP
nmulligan@cohenandmalad.com

Nicholas B. Reuhs
ICE MILLER LLP (Indianapolis)
nick.reuhs@icemiller.com

Joshua L. Simmons
Kirkland & Ellis LLP
joshua.simmons@kirkland.com

Brett Barrett Thomas
Cohen & Malad, LLP
bthomas@cohenandmalad.com

Jeanna Wacker
Kirkland & Ellis LLP
jeanna.wacker@kirkland.com

Diana M. Watral
Kirkland & Ellis LLP
diana.watral@kirkland.com